



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,237	03/10/2000	Michael M. Becker	GP068-03.CN1	5771

21365 7590 04/23/2002

GEN PROBE INCORPORATED  
10210 GENETIC CENTER DRIVE  
SAN DIEGO, CA 92121

EXAMINER

LACOURCIERE, KAREN A

ART UNIT	PAPER NUMBER
----------	--------------

1635

DATE MAILED: 04/23/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/523,237

Applicant(s)

BECKER ET AL.

Examiner

Karen Lacourciere

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 442-491 is/are pending in the application.
- 4a) Of the above claim(s) 442-452, 468-471 and 485-488 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 453-467, 472-484 and 489-491 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Application/Control Number: 09/523,327  
Art Unit: 1635

Page 2

## DETAILED ACTION

### *Election/Restrictions*

Applicant traverses the withdrawal of claims 442-457, 468-471 and 485-488 in the prior Office action (mailed 11-06-01) and provisionally agrees to pursue the subject matter of claims 458-467, 472-484, 489-491 in Paper No. 15. The traversal is on the ground(s) subject matter of claims 442-491 should be examined as a whole because the Examiner has not established that the claimed inventions are related as a combination/subcombination and further, that the Examiner has not demonstrated that the particulars of the subcombination are not required for patentability of the combination.

Applicant argues that, although in claim 458 there is no requirement that the claimed kit comprise a promoter sequence, as required by claims 442-457, the kit claimed in claim 458 may include a primer which comprises a promoter, based on the specification at page 22-23.

This is not found to be persuasive because the combination of claims 442-457, requires a promoter sequence, which could confer patentability without the particulars of the subcombination of claims 458-467, 472-484 and 489-491, even though the subcombination could include the particulars of the combination (ie. a promoter primer) and this subcombination has utility in other combinations, as, for example, a primer in a kit wherein a promoter is not required in the kit.

Applicant further argues that the particulars of the subcombination of claims 468-471 depend directly or indirectly from claim 458 and claims 485-448 depend directly or

indirectly from claim 474 and therefore, the particulars of the subcombinations of claims 474 and 458 are required in the combination. This is not found persuasive because the added limitation of adding an affinity capture probe to the combination of claims 468-471 and 485-488 could confer patentability on this combination, separate from the particulars of the subcombination. Patentability of the combination could rest entirely with the capture probe, rather than the particulars of the subcombination of claims 458-467, 472-484 and 489-491, which would have separate utility in a kit that does not require a capture probe.

Given the differences in the particulars of the combination versus the subcombinations, as set forth in the Office action mailed 11-06-01, a separate search would be required.

The requirement is still deemed proper and is therefore made FINAL.

Claims 442-457, 468-471 and 485-488 are maintained as withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to an invention constructively nonelected by original presentation, and confirmed in Applicants response filed Feb. 7, 2002, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

This application contains claims 442-457, 468-471 and 485-488 drawn to an invention constructively nonelected by original presentation and provisionally nonelected with traverse in Paper No. 15. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

***Double Patenting***

The provisional rejection of claims 422-441 under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 444-465 of co-pending application Serial Number 09/565,427 is withdrawn in view of the cancellation of claims 42-441 by Applicant in the response filed Sept 24, 2001.

***Claim Rejections - 35 USC § 102***

The rejection of record under 35 U.S.C. 102(e) as being anticipated by Van Gemen et al., U.S. Patent No. 5,679,553, is withdrawn in response to the Declaration filed 02-07-02, under 37 CFR §1.131 which antedates the reference Van Gemen et al.

***Response to Arguments***

Applicant's arguments filed on 02-07-02 have been considered but are moot in view of the new ground(s) of rejection.

***New Grounds of Rejection***

Claims 459, 464-467 and 481-484 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 459 recites the limitation "said modified ribonucleotides" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 464 and claims dependent on claim 464 are indefinite due to the recitation "an amplification product generated using said amplification oligonucleotide over a base sequence contained in any non-target nucleic acid present in said sample". It is unclear what is encompassed by "using" an oligonucleotide "over" a base sequence.

Claim 481 and claims dependent on claim 481 are indefinite due to the recitation "an amplification product generated using said amplification oligonucleotide over a base sequence contained in any non-target nucleic acid present in said sample". It is unclear what is encompassed by "using" an oligonucleotide "over" a base sequence.

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 458-460, 464-466, 472-477, 481-483 and 489-491 are rejected under 35 U.S.C. 102(b) as being anticipated by Ullu et al (JBC, Vol. 268, No. 18, June 25, 1993, pages 13068-13073).

Ullu et al. disclose unlabeled RNA oligonucleotide primers that comprise 10 2'-O-methyl modified ribonucleotides. The primers disclosed by Ullu et al. hybridize to a target sequence in the trypanosome splice leader sequence. The primers disclosed by Ullu et al. would additionally act as probes that bind to an amplification product that is complementary sequence to the target sequence. Ullu et al. disclose using multiple 2'-O-methyl primers targeted to the trypanosome leader sequence together, such that primers anneal at sites 5' or 3' of target sites. Ullu et al. disclose their oligonucleotides with other reagents for performing an amplification reaction, for example, with other

Art Unit: 1635

primers and in a solution. Ullu et al. do not explicitly recite their reagents are a "kit", however, they disclose all of the elements of the claimed "kit" together and meet all of the physical limitations of the claimed kit. Packaging the elements disclosed by Ullu et al. and calling it a "kit" and even adding "instructions" would not distinguish or change the modified primers disclosed by Ullu et al. The claim limitation of a kit, which is a product, and instructions for amplification, are not given patentable weight. Being in a kit or with instructions is not necessary for using the claimed oligonucleotide primers and has no significance to the molecular structure of the claimed oligonucleotides.

Therefore, Ullu et al. anticipates claims 458-460, 464-466, 472-477, 481-483 and 489-491.

Claims 458, 461, 462, 472, 473, 474, 475, 478, 479, 480, 489-491 are rejected under 35 U.S.C. 102(e) as being anticipated by Cook et al. (U.S. Patent No. 5,914,369, cited on PTO form 1449, filed April 1, 2002).

Cook et al. disclose 2'-O-methyl oligonucleotides which hybridize to a target nucleic acid sequence. Cook et al. disclose these oligonucleotides in an assay wherein the target is synthesized using T7 RNA polymerase and nucleotide triphosphates, prior to testing the hybridization of multiple 2'-O-methyl oligonucleotides to the target nucleic acid sequence. Cook et al. do not explicitly recite their reagents are a "kit", however, they disclose all of the elements of the claimed "kit" together and meet all of the physical limitations of the claimed kit. Packaging the elements disclosed by Cook et al. and calling it a "kit" and even adding "instructions" would not distinguish or change the

modified primers disclosed by Cook et al. The claim limitation of a kit, which is a product, and instructions for amplification, are not given patentable weight. Being in a kit or with instructions is not necessary for using the claimed oligonucleotide primers and has no significance to the molecular structure of the claimed oligonucleotides.

Therefore, Cook et al. anticipates claims 458, 461, 462, 472, 473, 474, 475, 478, 479, 480, 489-491.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Thursday 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere  
April 17, 2002

  
**ANDREW WANG**  
**PRIMARY EXAMINER**